

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year) See form PCT/ISA/210

Applicant's or agent's file reference:

BHC031082-WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2005/000067

International filing date (day/month/year)

07.01.2005

Priority date (day/month/year)

10.01.2004

International Patent Classification (IPC) or both national classification and IPC

A61K9/08, A61K31/44, A61K31/47, A61K31/53

Applicant

BAYER HEALTHCARE AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY.

International application No.

PCT/EP2005/000067

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 11

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 11

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2005/000067

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims		YES
	Claims	1-10	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO
2. Citations and explanations:			
1. Reference is made to the following documents:			
D1: US-A-4 402 941 (VAILLANCOURT ET AL) 6 September 1983 (1983-09-06)			
D2: CÉLINE LAFFONT ET AL: "Licking behaviour and environmental contamination arising from pour- on ivermectin for cattle" INT. J. OF PARASITOLOGY, vol. 31, 2001, pages 1687-1692, XP008057275			
D3: WO 00/74714 A (GLENN, GREGORY, M) 14 December 2000 (2000-12-14)			
D4: WO 01/08682 A (ASTA MEDICA AG; BAYER AG, AWD.PHARMA GMBH & CO. KG) 8 February 2001 (2001-02-08)			
D5: US-B1-6 191 143 (WATTS JEFFREY L ET AL) 20 February 2001 (2001-02-20)			
D6: WO 97/42954 A (PHARMACIA & UPJOHN COMPANY; WATTS, JEFFREY, L; WARDLEY, RICHARD, C; ST) 20 November 1997 (1997-11-20)			
D7: WO 99/62519 A (BAYER AKTIENGESELLSCHAFT; KUHN, MATTHIAS; ROHDE, BETTINA; SCHNABEL, HE) 9 December 1999 (1999-12-09)			
D8: WO 02/14288 A (BAYER AKTIENGESELLSCHAFT; GREIF, GISELA; BILL, IRIS; MUNDT, HANS-CHRIS)			

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

21 February 2002 (2002-02-21)

D9: WO.03/101422 A (BAYER AKTIENGESELLSCHAFT;
MERTIN, DIRK; EDINGLOH, MARKUS; DAUBE, GERT;)

11 December 2003 (2003-12-11)

D10: EP-A-0 659 410 (ASTA MEDICA
AKTIENGESELLSCHAFT) 28 June 1995 (1995-06-28)

D11: WO 2004/047795 A (BAYER HEALTHCARE AG; MERTIN,
DIRK; BEDDIES, GERALD; BECKER, SABINE)

10 June 2004 (2004-06-10)

2. Novelty PCT Article 33(2))

The subject matter of claims 1-10 is not novel.

2.1. The principle of the present application is described in D1 (see column 2, lines 40-48), D2 and D3 (see claim 19, and page 12, lines 1-16). The subject matter of claims 1-3 and 9, 10 is therefore still novel in the light of D1, D2 and D3.

2.2. D4-D10 relate to the disclosure of compositions which are suitable for topical application.

- D4 is prejudicial to the novelty of the subject matter of claims 1-3, 5, 9 and 10 (see page 15)
- D5: is prejudicial to the novelty of claims 1-3, 5, 8, 9 and 10 (see the examples)
- D6 is prejudicial to the novelty of the subject matter of claims 1-3, 5, 9 and 10 (see page 10)
- D7 is prejudicial to the novelty of the subject matter of claims 1-3, 7, 9, 10 (see page 5)
- D8 is prejudicial to the novelty of the subject matter of claims 1-3, 8-10 (see examples 1-3)
- D9 is prejudicial to the novelty of the subject matter

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

of claims 1-6, 9 and 10 (see the examples)

- D10 is prejudicial to the novelty of the subject matter
of claims 1-4, 9-10 (see page 8)

3. Inventive step (PCT Article 33(3))

Documents D1-D3 and D4-D10 can be regarded as being particularly relevant to the inventive step (PCT Article 33(3)). Indeed, these documents provide a solution to the same problem as the present application. The applicant is therefore asked to demonstrate any effects which could not have been predicted, taking into consideration the closest prior art.

4. The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claim 10 in its present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. VI

Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO2004/047795	10.06.2004	18.11.2003	28.11.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure
referring to non-written disclosure
(day/month/year)

See form 210

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box III

Claim 10 relates to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently, no expert opinion has been established in respect of the industrial applicability of the subject matter of said claim (PCT Article 34(4)(a)(i)).

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year)	See form PCT/ISA/210
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Applicant's or agent's file reference BHC031082-WO		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/EP2005/000067	International filing date (day/month/year) 07.01.2005	Priority date (day/month/year) 10.01.2004	
International Patent Classification (IPC) or both national classification and IPC A61K9/08, A61K31/44, A61K31/47, A61K31/53			
Applicant BAYER HEALTHCARE AG			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language ,
_____ , which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 11

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 11

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-10	NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations:

1. Reference is made to the following documents:

- D1: US-A-4 402 941 (VAILLANCOURT ET AL)
6 September 1983 (1983-09-06)
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environmental contamination arising from pour-
on ivermectin for cattle" INT. J. OF
PARASITOLOGY, vol. 31, 2001, pages 1687-1692,
XP008057275
- D3: WO 00/74714 A (GLENN, GREGORY, M)
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- D4: WO 01/08682 A (ASTA MEDICA AG; BAYER AG,
AWD.PHARMA GMBH & CO. KG) 8 February 2001
(2001-02-08)
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- D6: WO 97/42954 A (PHARMACIA & UPJOHN COMPANY;
WATTS, JEFFREY, L; WARDLEY, RICHARD, C; ST)
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MATTHIAS; ROHDE, BETTINA; SCHNABEL, HE)
9 December 1999 (1999-12-09)
- D8: WO 02/14288 A (BAYER AKTIENGESELLSCHAFT;
GREIF, GISELA; BILL, IRIS; MUNDT, HANS-CHRIS)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

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MERTIN, DIRK; EDINGLOH, MARKUS; DAUBE, GERT;)

11 December 2003 (2003-12-11)

D10: EP-A-0 659 410 (ASTA MEDICA
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D11: WO 2004/047795 A (BAYER HEALTHCARE AG; MERTIN,
DIRK; BEDDIES, GERALD; BECKER, SABINE)

10 June 2004 (2004-06-10)

2. Novelty PCT Article 33(2))

The subject matter of claims 1-10 is not novel.

2.1. The principle of the present application is described in D1 (see column 2, lines 40-48), D2 and D3 (see claim 19, and page 12, lines 1-16). The subject matter of claims 1-3 and 9, 10 is therefore still novel in the light of D1, D2 and D3.

2.2. D4-D10 relate to the disclosure of compositions which are suitable for topical application.

- D4 is prejudicial to the novelty of the subject matter of claims 1-3, 5, 9 and 10 (see page 15)

- D5: is prejudicial to the novelty of claims 1-3, 5, 8, 9 and 10 (see the examples)

- D6 is prejudicial to the novelty of the subject matter of claims 1-3, 5, 9 and 10 (see page 10)

- D7 is prejudicial to the novelty of the subject matter of claims 1-3, 7, 9, 10 (see page 5)

- D8 is prejudicial to the novelty of the subject matter of claims 1-3, 8-10 (see examples 1-3)

- D9 is prejudicial to the novelty of the subject matter

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

of claims 1-6, 9 and 10 (see the examples)

- D10 is prejudicial to the novelty of the subject matter
of claims 1-4, 9-10 (see page 8)

3. Inventive step (PCT Article 33(3))

Documents D1-D3 and D4-D10 can be regarded as being particularly relevant to the inventive step (PCT Article 33(3)). Indeed, these documents provide a solution to the same problem as the present application. The applicant is therefore asked to demonstrate any effects which could not have been predicted, taking into consideration the closest prior art.

4. The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claim 10 in its present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/EP2005/000067

Box No. VI **Certain documents cited**

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO2004/047795	10.06.2004	18.11.2003	28.11.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

See form 210

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/EP2005/000067

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box III

Claim 10 relates to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently, no expert opinion has been established in respect of the industrial applicability of the subject matter of said claim (PCT Article 34(4)(a)(i)).